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Interview with Joshua Lederberg, Professor Emeritus, Rockefeller University

What do you think of the recently published articles in various journals directed to the new administration, highlighting issues such as biological terrorism as an issue that needs to be addressed?

They want to make sure the new administration is as well prepared as the previous administration. President Clinton took very personal, very well-informed interest in these matters. He put out at least two presidential decision directives. If the new administration is as attentive to these matters as Mr. Clinton was, we'll be on track.

Do you have any sense of where this administration stands on the issue of biological weapons?

Not yet. There's no reason to doubt it, but they have a lot of other things on their minds. I would say the reconstruction of the National Security Council that Condoleezza Rice has been establishing makes it less likely that they will be the centerpoint, but on the other hand, other agencies are carrying the ball, such as Force Command, within the Department of Defense (DoD) structure. A lot of things have changed. Whether they will be adequate structures, I don't know. They will probably be different from what we have.

In your book you mention a 1998 speech by President Clinton that out-

lines his directives. How well do you think those directives have been carried out? How far along do you think we are in committing to them?

It's still pretty much in disorder. We don't know what the national structures are going to be. It's a very difficult problem because it does involve at minimum law enforcement, which would be Department of Justice, FBI, and crisis anticipation, especially dealing with bioterrorism.

I think it's something that will still have to be worked out over the next months. There are a lot of issues, including the role of ForceCom. I talked to the Secretary of Defense [Rumsfeld] briefly about it, and he does understand the responsibility of DoD even for civil preparedness, but his whole structure still has to be appointed. We don't have the assistant secretaries in place yet who will actually be involved. So all that has to be redone.

There is an issue of focusing both on preparedness and response. Which do you think the new administration should focus on more closely?

There are definitional issues. There's not much we really know about prevention. On the bioterrorism side, what the FBI does with its penetration of groups is important. That still needs to be balanced against civil liberties issues. If they could tap every telephone in the country at liberty

and had the resources to record it, they would probably be ahead a notch or two. But they would be so drowned in data, they couldn't possibly analyze it. But people sometimes talk in that vein.

There are a lot of aborted efforts at terrorist attack they have managed to [infiltrate]. We've had these border crossings, both in Maine and Seattle. It's incredible that they were able to catch those folks. You would have thought they just got the tip of the iceberg, but it really appears they got the principal culprits on those occasions. If they can keep up that good a record, that's important prevention. But still, no one believes that can work in every case.

We need to recognize the fact that there will be attacks of varying degrees of sophistication, mostly pretty crude, mostly not likely to be the top of the mark in terms of skill and finesse and technical insight, but even by accident, they could go a lot further than one might expect. Aum Shirinkyo made a real bungle, but it's hardly a guarantee that malevolent efforts are bound to fail.

I think we need a balanced program. We need to assess what the opportunities are for intervention. Some things are just so obvious. Being prepared to cope with a release of anthrax is pretty high on the list. It's almost equivalent to temptation, not to be prepared for those kinds of events. After that it gets very difficult, because there is a much wider range of agents than we could possibly have vaccines for. But they are also much more difficult to procure and to handle. At this stage in the development of these capabilities, I don't think we're going to leapfrog to the second or third generation without seeing some of the more primitive efforts in the first instance. So that's what I would focus on, since that's what we are able to do. But we still don't

have a well-structured program, say of antibiotic stockpile. We still have a very messy situation about what kinds of anthrax vaccines can be redeveloped. It [anthrax vaccine] is really a very old entity that has the advantage of long experience with it. We have every reason to believe it's perfectly safe. It's very clumsy to use; it takes at least three shots. It takes several weeks to get full immunity. We certainly ought to be able to do better than that with the new generation. But it will probably cost, by the time we're done, a couple hundred million dollars before we can beat the far side of it. That's assuming no major glitches are in our way.

Because biological agents have dual usage, how much involvement do you think the government should have in the R&D process? How much should the government work and be involved in coming up with these vaccines?

If the government doesn't do it, nobody will. This is not dual use. There is no civilian market for anthrax vaccines. There is no civilian market for plague vaccine. There's very limited interest in the encephalitic viruses. It does happen, but these are all quite rare diseases under normal circumstances, so making appropriate preparations for them is really only in the context of civil preparedness against biological attack. That's a government responsibility. Some of it is done within government labs. But in the past years they've been decimated; they're not what they used to be. They need to be re-funded adequately to do their job.

We have heard elsewhere that there is adequate funding, but that the lack of coordination has led to chaos and inefficient use of the available funding. Do you agree?

It's so hard to put your finger on it. Until that money is actually in the pipeline, you can't say there is enough. There are high expectations. Probably a fair amount of it is going to things that aren't too worthwhile. There's an enormous amount of money going into biosensors, which will still take two or three years before it crystallizes into an explicit program. There doesn't begin to be enough to cover the vaccine development. There's enough for the beginning of antibiotic stockpiling, but not for a full-blown program. Even the planning for this is in a pretty primitive stage.

What is the possibility for FDA involvement? Could the FDA have some sort of fast-track approval for the vaccines?

Under current FDA doctrine, you have a catch-22 that nothing, no new vaccine, could be approved unless it had demonstrated clinical efficacy in the context where it would be applied. In other words, you would have to have experiments that would show that it would defend a civilian population against an aerosol attack by bioterrorists. That's not an experiment we have any way of doing. But their hands are tied in terms of existing regulations. They've been through a process that is finally reaching some culmination. They've had hearings, they've had request for comment, and they've had draft proposals that would alter that doctrine. For this specific case, though, we're talking about material for public health emergency that could be validated if they go through all the safety precautions that are required of any other vaccine. They need to demonstrate the vaccine to be efficacious in treating the disease under experimental conditions in animals. Using experimental subjects, it needs to be shown to raise antibodies in humans. So we'd no longer be required to

do the impossible, which would be to expose 100 human volunteers to anthrax to see whether the vaccination protected them against inhalation anthrax. Even that wouldn't be a precise alignment in a clinical situation. So it's taking a very, very long time, but it seems to be coming to some fruition, at least where that would be permissible.

No one has argued there should be any other safety standards; if we're going to give something out even in a dire emergency, you'd want to do everything possible to ensure you weren't doing *any* harm and certainly not more harm than good. But it's been a serious dilemma how to encourage vaccine approval. So proxies for efficacy are a necessary step. That's as fast-track as we need.

Once a vaccine is approved, would the government be able to commandeer labs to produce them, as the government can commandeer ships in the Merchant Marine in terms of war? Can you see this as a possibility, with possibly an agreement the government will make with pharmaceutical companies to use their laboratories to produce these vaccines after a biological attack?

The trouble is, it takes too long to reconvert [the labs]. If you're talking about the anthrax vaccine, you could never use [the lab] for anything else again once you had anthrax in the facility. The FDA would never approve [it], no matter how you scrubbed it, for any other application. So it would be irrevocable. A better track is a government-owned pharma, corporate-operated facility. That's been going around for years, but there's been a lot of resistance to it. The same elements in the pharmaceutical industry that have themselves declined to participate when they've been asked to make bids in the production of vaccines have also been part of the foot-

dragging process in enabling alternative routes. Some smaller companies have been interested in bidding, but none of the big ones even responded to requests for bids.

Is that because of the lack of profit incentive?

There's not enough [incentive]. Working with the government involves horrendous complications and they do very well, thank you, with their own private efforts. So we have much smaller and much less experienced firms beginning to make bids. There is a procurement that's been out for small-pox vaccine, for example, which used to be produced for five cents a dose, but under ancient standards. Under contemporary standards, it's going to be \$50 or \$100 a dose. That's what they've been coming in with, and there's been no alternative to it. I don't know if there's any way around that. There's so little experience in this military-civilian interface in the health-related area. Parties are suspicious of one another. Mostly they don't understand one another, which inflates the costs enormously. But it is starting to happen, so it's not a hopeless situation.

In terms of response, we've talked about the medical effects of a biological attack, but what about the psychological effects?

We had a conference on that six or eight months ago with a lot of wise words on the need for preparedness and how to deal with the social impact of attack. I think the short answer is exercise, exercise, exercise. Have different branches of government able to cooperate. The place where coordination may be most critical is in the information activities. If [different branches of government] start giving discordant information or don't respond to

what CNN will be putting out by way of provocation, I think they will only fan the flames of panic and disorder. So credibility, reliability, promptness, and consistency are the main words there, but you're never going to achieve that without exercising who's going to undertake which responsibilities under these circumstances. There needs to be prior information to the public health authorities of different cities.

In New York City, there's been an exemplar. Jerry Hauer was the director of emergency management in New York City for many years. Mayor Giuliani provided a lot of support to try and provide this framework. [Hauer] conducted a lot of tabletop exercises, bringing in every branch of government that would be relevant to it. They had bulletins prepared beforehand on various kinds of agents; they had different elements of government prepared to deal with them. We had a commissioner of health who was apprised to it. We had the police department and fire department, both of which played important roles as first responders. [Hauer] had a pretty smoothly working team, but it would take half a dozen exercises before he could get there. Those are the main messages that come out of it. Having people stampeding, trying to get out of the isle of Manhattan after an attack could totally disrupt the public health services they were trying to offer at the same time. The amount of panic could exceed what the direct injury would be. That is very important.

There is another issue: prevention versus paranoia. If we get so worked up about the possibility of an attack, could a hoax wreak as much havoc as an actual attack?

I think we have to worry a lot about the mass media; they tend to glamorize these issues, if I can use a kind word. They may also help make it seem more attractive to would-be perpetrators. I certainly don't want to be part of that process. And some

degree of temperance on the part of the media is a very important part of prevention. Other people say if you don't raise the issue, you'll never get any political response, but I've tried to be low-key in how I present it.

The US has an official policy of not granting concessions to terrorists. Do you think the possibility that a bioterrorist attack, which could endanger hundreds of thousands of lives, could warrant a possible change in US policy?

I'm not sure I'm the one to comment on that. A biological attack is much more likely to be one intended to kill the state or to kill as many people as possible out of some element of revenge than it is out of compellence. In some respects, there is very low predictability; a biological threat can be quite open-ended with what the actual consequences are. It's not what you're looking for if you want a lever to pry loose some element of policy.

So you think the perpetrators of a biological attack just want to do the act rather than force some sort of policy change?

That's where terrorism has changed. Terrorism has mostly focused on theater, on demonstrations, and maybe taking hostages. So those are, historically, negotiation scenarios. I don't know where to begin on how I would model negotiations for something as large but unpredictable an outcome as a biological attack. I think people making a biological attack may be trying to kill and show what they can do, out of revenge or their crazy motives, for example the attacks on the Oklahoma City federal building and the World Trade towers. Those are not negotiating stances.

Related to this is the question of deterrence. We have an international convention, the Biological Weapons Convention, that has not received universal support. There has been a proposal to make creation or possession of biological weapons an international crime. Do you think that would provide enough of a deterrent?

It might add to it. I don't think it will solve the problem, but I think it is an element of it, and it's an element of seriousness of purpose, giving some handle for enforcement. If circumstances come up where there are potential culprits, we'd have something very definite, some legal process by which to apprehend them and pursue them. As it is now, I think, de facto, the US has claimed extraterritoriality on certain categories of terrorist actions and is likely to do that in the event of a biological threat as well. But we don't have that around the rest of the world, so we don't really have a forum in which to insist on the enforceability of the BW Convention, even against individuals. That's Matt Meselson's proposal; it would be implemented by having the force of law within individual states.

Under those circumstances, I don't see any reason why the US should not be a party to it. I'm not certain whether we're ready to have an international court; we don't know what its standards would be or how to avoid its being used for political demonstrations. We've had US presidents put up on war crimes trials of one sort or another. An international court could be dragged into that kind of theater. I think that may be one of the reasons for reluctance for subscription to it. But I distinguish that from what Dr. Meselson's proposal is; it seems a completely sound one. It doesn't solve the problem, but I think consolidating some issues of resolve that we really do take BW terrorism seriously.

Regarding international cooperation, you had stated to the UN Committee on Disarmament that international cooperation is one area that is lacking in dealing with biological weapons. Is that still the case?

Look at enforcement with regard to Iraq. That coalition is falling apart at the UN Security Council level and there are also many countries that prefer enhancing their trade with Iraq and getting Iraqi oil over enforcing the Convention. So we're in trouble. We were part of that trouble some years ago; we were looking the other way

when Iraq was using chemical weapons against Iran and I think we set the scene for many later troubles by taking such a cynical view at that time.

If you could suggest one thing to the government that it should focus on, or one thing that needs improving, what would that be?

Coordination of the different response agencies. At this point, structure is all-important. There are lots of resources available or could be made available if [the government] could develop some concerted cooperative effort, but it is so fragmented.

In 1958, Joshua Lederberg was awarded the Nobel Prize for his discoveries concerning genetic recombination and the organization of the genetic material of bacteria. Shortly afterward he joined the new Department of Genetics at Stanford University's School of Medicine. In 1978, he was appointed President of Rockefeller University. He became a Professor Emeritus in 1990. He is a member of the National Academy of Sciences and continues to research, lecture, and serve on a number of advisory panels.